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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,852	07/03/2003	Joel S. Douglas	7404-543	4411

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WOODARD, EMHARDT, MORIARTY, MCNETT & HENRY LLP  
111 MONUMENT CIRCLE, SUITE 3700  
INDIANAPOLIS, IN 46204-5137

EXAMINER
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APANIUS, MICHAEL

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 08/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/612,852	DOUGLAS ET AL.	
	Examiner	Art Unit	
	Michael Apanius	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 July 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 14-20 and 86-102 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14-20 and 86-102 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>7/13/03, 10/7/04, 11/29/04, 12/21/05, 2/23/06, 7/14/06</u>                | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election without traverse of Group II in the reply filed on 7/14/2006 is acknowledged. The cancellation of claims 1-13 and 21-85 and the addition of new claims 86-102 are acknowledged.

### ***Specification***

2. The disclosure is objected to because of the following informalities: at page 11, line 1, it appears that "22" should be --20-- and at page 14, line 21, it appears that "24" should be --24"--. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 14-20, 97 and 99-102 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The original disclosure fails to provide sufficient support for the claimed method being carried out on a "non-

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digit body part", "an earlobe", "a limb", or "a region of skin where nerve density is low and supply of body fluid is low" as set forth in claims 14, 20, 97, 99 and 102.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 86-98 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. At claim 86, line 2, the meaning of "an alternate site" by itself is unclear because a non-alternate site has not been previously recited in the claim.

### ***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 86-90, 95, 96 and 98 rejected under 35 U.S.C. 102(b) as being anticipated by Garcia et al. (US 4,637,403). Garcia discloses a method (columns 7-9), comprising: positioning a lancing device (10) in contact with an alternate site, wherein the lancing device houses a disposable (12) that include a lancet (90) and a test strip (94); forming an incision in the alternate site with the lancet of the disposable; and

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analyzing the body fluid from the incision with the test strip of the disposable. Note that an alternate site as stated in the claim can be considered a finger tip.

9. In regards to claim 87, the method further comprises expressing the body fluid from the incision with the lancing device before said analyzing.

10. In regards to claim 88, the lancing device includes a stimulator member (the bottom member of the lancing device as shown in figure 4); and said expressing includes pressing the stimulator member around the incision. Note that the bottom of the lancing device is pressed against the finger before actuation and this pressure will inherently aid blood expression to some degree.

11. In regards to claim 89, the method further comprises removing the disposable from the lancing device after said analyzing; discarding the disposable after said removing; and loading a fresh disposable into the lancing device (see figure 3).

12. In regards to claim 90, the disposable includes a capillary and the method further comprises drawing body fluid into the test strip via capillary action (column 8, lines 18-22).

13. In regards to claims 95 and 96, the analysis is performed using an optical or electrochemical technique (column 8, lines 28-33).

14. In regards to claim 98, the lancing device remains in contact with the alternate site during said forming and said analyzing.

***Claim Rejections - 35 USC § 103***

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. Claims 14-20, 97, 99, 101 and 102 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garcia et al. (US 4,637,403) in view of Cusack et al. (US 5,314,441). Garcia discloses the limitations of the claims as noted above. In addition, Garcia discloses moving a capillary from a first position to a second position and a test strip that is disposed along the capillary at the end of the sampling device proximal the skin. The test strip is also considered to be disposed at an end of the sampling device proximal the skin. However, Garcia does not expressly disclose placing the sampling device on a non-digit body part, an earlobe, a limb, or a region of skin where nerve density is low and the supply of body fluid is low. Cusack teaches taking blood samples on alternative sites such as a foot, arm or leg for the purpose of obtaining blood samples from neonates or persons with poor circulation (column 1, lines 17-21). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have placed a sampling device on an arm or leg as taught by Cusack in the method of Garcia in order to obtain a blood sample from neonates or persons with poor circulation.

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17. Claims 91-93 and 100 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garcia et al. (US 4,637,403) as modified by Cusack et al. (US 5,314,441) as applied to claims 14-20, 86-90, 95-99, 101 and 102 above, and further in view of Smith (US 5,108,889). Garcia as modified by Cusack does not expressly disclose detecting a drop of the body fluid from the incision is sufficient with a drop sensing mechanism. Smith teaches a drop sensing mechanism that electrically detects the drop and then alerts a user of drop sufficiency for the purpose of ensuring that an adequate sample is obtained for testing (column 25, last paragraph). Note that since the detection occurs during the drawing of the sample, that the detecting step first occurs before a last portion of the drawing step. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have used a drop sensing mechanism as taught by Smith in the method of Garcia as modified by Cusack in order to ensure that an adequate sample is obtained before testing.

18. Claim 94 is rejected under 35 U.S.C. 103(a) as being unpatentable over Garcia et al. (US 4,637,403) as modified by Cusack et al. (US 5,314,441) and Smith (US 5,108,889), as applied to claims 91-93 and 100 above, and further in view of Morfeld et al. (US 4,562,842). Garcia as modified by Cusack and Smith does not expressly disclose optically detecting the drop. Morfeld teaches that it is known in the art to use an optical detector to determine a sufficient volume of liquid (column 4, lines 3-12). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have used an optical detector as taught by Morfeld in the method of

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Garcia as modified by Cusack and Smith because it is an art-recognized equivalent to an electrical detection means.

**Conclusion**

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Apanius whose telephone number is (571) 272-5537. The examiner can normally be reached on Mon-Fri 8:30am-5pm.

20. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

21. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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